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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,934	10/26/2001	Herve E. Recipon	DEX-0245	1406

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EXAMINER
SPIEGLER, ALEXANDER H

ART UNIT	PAPER NUMBER
1637	7

DATE MAILED: 08/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/034,934	RECIPON ET AL.	
	Examiner	Art Unit	
	Alexander H. Spiegler	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-17* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1 ☐ Certified copies of the priority documents have been received.

2 ☐ Certified copies of the priority documents have been received in Application No. _____ .

3 ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5 and 7-9, drawn to an isolated nucleic acid molecule, a vector comprising said molecule, a host cell comprising said vector, and a method for producing a polypeptide using said molecule, classified in class 536, subclass 23.1, class 435, subclasses 69.1, 320.1, and 325, for example.

II. Claim 6, drawn to a method for determining the presence of a lung specific nucleic acid, classified in class 435, subclass 6, for example.

III. Claims 10 and 11, drawn to an isolated polypeptide, classified in class 530, subclass 350, for example.

IV. Claim 12, drawn to an antibody, classified in class 530, subclass 387.1, for example.

V. Claim 13, drawn to a method for determining the presence of a lung specific protein, classified in class 435, subclass 7.1, for example.

VI. Claim 14 (in part), drawn to a method for diagnosing and monitoring the presence and metastases of lung cancer using a nucleic acid, classified in class 435, subclass 4, for example.

VII. Claim 14 (in part), drawn to a method for diagnosing and monitoring the presence and metastases of lung cancer using a polypeptide, classified in class 424, subclass 277.1, for example.

VIII. Claim 15 (in part), drawn to a kit comprising a means for determining the presence of a nucleic acid molecule, classification undeterminable; classification determinable on means.

IX. Claim 15 (in part), drawn to a kit comprising a means for determining the presence of a polypeptide, classification undeterminable; classification determinable on means.

X. Claim 16, drawn to a method of treating a patient with lung cancer by administrating an antibody, classified in class 424, subclass 130.1, for example.

XI. Claim 17 (in part), drawn to a vaccine comprising a polypeptide, classified in class 514, subclass 2, for example.

XII. Claim 17 (in part), drawn to drawn to a vaccine comprising a polynucleotide, classified in class 514, subclass 44, for example.

2. The claims of Group I-XII are drawn to a multitude of nucleic acids, polypeptides, antibodies thereto and methods which use these compounds. Each of the different nucleic acids, polypeptides, antibodies and methods of use are independent and distinct because no common structural or functional properties are shared. Accordingly, these claims are subject to restriction under 35 U.S.C. § 121.

Upon election of one of Groups I-XII, Applicant is additionally required to elect a **single** nucleic acid, polypeptide, or antibody. This requirement is not to be construed as a requirement for an election of species, since each of the compounds is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

3. The inventions are distinct, each from the other because of the following reasons:

A) The inventions of Groups I, III, IV, VIII, IX, XI and XII are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acid of Group I is composed of nucleotides linked in phospodiester bonds and arranged in space as a double helix. The polypeptide of Group III is composed of amino acids linked in peptide bonds and arranged spatially in a number of different tertiary structures including alpha helices, beta-pleated sheets, and hydrophobic loops (transmembrane domain). The antibody of Group IV is composed of amino acids linked in peptide bonds and arranged spatially in a very specific tertiary structure that allows that antibody to specifically bind to particular regions, i.e., epitopes, of the encoded polypeptide. Further, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associated via disulfide bonds into a Y-shaped symmetric dimer. The kits of Groups VIII and IX do not recite any structural language. The vaccines of Groups XI and XII comprise additional reagents/or agents inherent to vaccines that are not present in the products of Groups I, III and IV (e.g., a tumor-specific vectors, autologous host cells for circumventing rejection, etc.). It is also noted that Group XI comprises a polypeptide, and Group XII comprises a polynucleotide, each differing in structure from one another (see discussion above). Furthermore, the products of Groups I, III, IV, VIII, IX, XI and XII can be used in materially different processes, for example, the nucleic acid of Group I can be used in hybridization assays, the antibody of Group IV can be used in immunoassay, the polypeptide of Group III can be used to make fusion protein with an enzymatic function, the kits of Groups VIII and IX can be used to detect the presence of nucleic acids and polypeptides, respectively, but do not necessarily have to be hybridization assays, and

the vaccines of Group XI and XII function to prevent a condition from occurring. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. It is also noted, each of the above Groups is classified differently (see above). Accordingly, because the claimed products are different chemical entities having differing biochemical structures, modes of operation, functions, and effects, the inventions of Groups I, III, IV, VIII, IX, XI and XII are patentably independent and distinct from each other.

B) Inventions I and (II and VI) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of Group I could be used in an entirely different method, such as in the recombinant production of the polypeptide or in an amplification reaction, rather than in the methods of Group II or VI.

C) Inventions I and (V, VII and X) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, and they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not required one for the other in that the nucleic acid of Group I is not required for the methods of Groups (V, VII and X).

D) Inventions II and (III, IV, VIII, IX, XI and XII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not required one for the other in that the products of III, IV, VIII, IX, XI and XII is not required for the method of Group II.

E) Inventions II, V-VII and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, and they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are directed to methods, which have different method steps, starting materials and goals. Accordingly, the methods are not capable of use together, and they have different modes of operation, different functions, and different effects.

F) Inventions III and (V and VII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide of Group III could be used in an entirely different manner, such as in methods of making a fusion protein or in a purification assay, rather than in the methods of Groups V or VII.

G) Inventions III and (VI and X) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not required one for the other in that the polypeptide of Group III is not required for the methods of Groups VI or X.

H) Inventions IV and (V-VII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not required one for the other in that the antibody of Group IV is not required for the method of Groups V-VII.

I) Inventions IV and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibody of Group IV could be used in an entirely different manner, such as in immunoassays, rather than in the method of Group X.

J) Inventions (V-VII) and (VIII, IX, XI and XII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not required one for the other in that the products of (VIII, IX, XI and XII) are not required for the methods of Groups (V-VII).

4. Because these inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-XII require different searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (703) 305-0806. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014. Applicant is also invited to contact the TC 1600 Customer Service Hotline at (703) 308-0198.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Alexander H. Spiegler
July 28, 2003

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

7/30/03